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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,427	08/04/2003	Jody L. Leers	CIL1974	4550
7590	01/05/2005		EXAMINER	
Sean A. Kaufhold P.O. Box 131447 Carlsbad, CA 92013			CHAPMAN, GINGER T	
			ART UNIT	PAPER NUMBER
			3761	
			DATE MAILED: 01/05/2005	

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/633,427	LEERS ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Ginger T Chapman	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
 THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 07 November 2004.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-10 is/are pending in the application.  
 4a) Of the above claim(s) 3,4 and 8 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1,2,5-7,9 and 10 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 5-7, 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elias (4,790,835) in view of Warner (3,648,700).

Elias discloses all aspects of the claimed invention with the exception of a peripheral lip integrally coupled to the cap member.

Elias discloses a male urinary device having a first proximal end (4), a second distal end (6), a perimeter wall (22) extending between first and second ends which provides for contact surface adjacent the skin of the user and an absorbent material (24) such as cotton or synthetic hydrophilic material positioned within the distal end portion (6). The device further comprises an elastomeric (col. 2, lines 40-45) adjustment band (8, 10) having substantial width so as to evenly distribute the pressure exerted upon the user's penis once the sheath is secured in place (col. 1, lines 57-62). The adjustment band (8, 10) defines the tubular member with the first and second ends being open and the distal portion (6) creating a cap member covering the second end such that a housing is defined (Fig. 2). The distal cap (6) is adapted for receiving the head of the user's penis (col. 2, lines 64-65). Upon placement of device, the inner surface of band (10) extends around the outer surface of tubular member (8) thus decreasing the diameter of the open

proximal end portion and thereby creating a side edge or lip (14) that extends outwardly away from second end when the sheath is secured about the user (col. 2, lines 65-68).

With regard to claims 1, 2, 9 and 10, Warner teaches an absorbent male device comprising an elastomeric material having a cap shaped for receiving the head of the user's penis (Figures 1 and 2 (10) and col. 1, lines 22-26) such that a housing is defined, the cap member further having a lip (16) which extends radially outwardly (col. 2, line 1) which in use will be pressed against the forepart of the glans penis (col. 2, lines 16-19) to retain the cap in place. The device includes an absorbent inner layer (14) and a band (24) to hold the device against inadvertent detachment (col. 2, line 24-25).

Therefore, to have formed the cap of Elias with the lip as taught by Warner, since Warner states at column 2, lines 16-19 that such a modification would allow the lip to be pressed against the glans penis and thus retain the cap in position when secured about the wearer and provide a cleaner and safer device for protecting the user would have been an obvious modification to one having ordinary skill in the art at the time the invention was made.

With regard to claim 5, the absorbent material positioned within the cap may be cotton (col. 3, lines 29-37).

With regard to claims 6 and 7, Elias discloses a urinary male diaper having an elastomeric adjustment band positioned generally adjacent to the first end of the tubular sheath with band (10) extending around an outer surface (8) of the tubular member. Additionally, Elias teaches it is known in the prior art to use thin draw strings or bands which localize the pressure exerted upon the user's penis (col. 3, lines 15-17) thus reducing comfort to the wearer and

causing the material forming the proximal end portion to bunch up around the skin of the user (col. 3, lines 23-27).

Accordingly, it would be desirable to provide a more comfortable device and reduce material bunching or rolling by adding a wider band to increase friction between the sheath and the penis. In particular, Elias teaches that the width of the band prevents the material of the sheath from bunching up around the skin of the user (col. 3, lines 23-27) and is more comfortable for the wearer than thin draw strings or bands (col. 3, lines 15-18). The overall length of the sheath is four inches (col. 3, lines 50-51) and as best depicted in Figure 3, the width of the band is one half of the overall length of the shield (col. 3, lines 9-17). In view of this known teaching, it would therefore be obvious to one having ordinary skill in the art at the time the invention was made to have fabricated the elastomeric band of prior art sheaths with substantial width as taught by Elias in order to provide a male urinary sheath that will not roll or bunch up and is comfortable to wear under clothing.

#### *Response to Arguments*

Applicant's arguments filed on November 7, 2004 have been fully considered but they are not persuasive.

With respect to Applicant's arguments that the lip of the claimed invention is not disclosed in the prior art and is of significant importance to the functionality of Applicant's device by fitting snugly along the base of the head of the penis, Warner discloses the claimed structural limitations of an absorbent collector device for removably positioning over a penis and having a cap with retaining lip, and therefore it would be inherent that the device is capable of collecting post urination discharge. It has been held that a recitation with respect to the manner

in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987), *In re Paulson*, 30 F.3d 1475 (Fed Cir: 1994), 31 USPQ2d 1671.

In response to Applicant's argument with regard to claims 6, 7 and 9, that teaching references from the male prophylactic art are not analogous to the male incontinence art because applicant's incontinence device differs from conventional prophylactics because applicant's device is made to be held onto a penis when the penis is substantially flaccid and therefore lead to functional differences between applicant's device and the prior art, it has been held that the determination that a reference is from nonanalogous art is twofold. First, we decide if the reference is within the field of the inventor's endeavor. If it is not, we proceed to determine whether the reference is reasonably pertinent to the particular problem with which the inventor was involved. *In re Wood*, 202 USPQ 171, 174.

In this case, Warner teaches the use of a lip and band to hold the absorbent device against inadvertent detachment. The examiner is relying on the Warner reference for the teaching of the use of a lip for a cap in a tubular sheath to aid in retaining the item on the wearer. The examiner is not replacing the entire structure of Elias with the cap and lip of Warner. Therefore it is the examiner's position that the combination of references has motivation, therefore the rejection stands as stated above.

### *Conclusion*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 3761

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginger T Chapman whose telephone number is (571) 272-4934. The examiner can normally be reached on Monday through Friday 8:30 a.m. to 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Schwartz can be reached on (571) 272-4390. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ginger Chapman  
Examiner, Art Unit 3761



  
Larry I. Schwartz  
Supervisory Patent Examiner  
Group 3700